MAY 21 2001

K003589

510 (k) Summary of Safety and Effectiveness

Product: BrainLAB´s Image Guided Surgery System VectorVision

510 (k) application: VectorVision²- amendment

Manufacturer:
BrainLAB AG
Ammerthalstrasse 8
85551 Heimstetten
Germany
Phone: +49 89 99 15 68 0
Fax: +49 89 99 15 68 33

What is new?
This 510 (k) application includes an amendment to the indications for use for BrainLAB´s image guided surgery system VectorVision´s specifying the Cranial, Spinal and ENT procedures.

Indications for use:
BrainLAB VectorVision is intended to be an intraoperative image guided localization system to enable minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space on a patient's preoperative image data being processed by a VectorVision workstation. The system is indicated for any medical condition in which the use of stereotactic surgery may be considered to be safe and effective and where a reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT, X-.ray or MR based model of the anatomy.

Example procedures include but are not limited to:

Cranial Procedures:
Cranial biopsies.
Tumor resections.
Craniotomies/ Craniectomies
Skull base procedures.
Thalamotomies/Pallidotomies

Spinal Procedures
Spinal implant procedures such as pedicle screw placement.

ENT Procedures:
Transphenoidal procedures.
Intranasal procedures.
Sinus procedures, such as Maximillary antrostomies, Ethmoidectomies, Sphenoidotomies/Sphenoid explorations, Turbinate resections and Frontal sinusotomies

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Substantial equivalence
The latest development of BrainLAB´s image guided surgery system VectorVision provided in this application has been verified and validated according to BrainLAB´s procedures for product design and development and the validation included clinical papers stating the safety and effectiveness of the VectorVision image guided surgery system for Cranial, Spinal and ENT procedures.

The information provided by BrainLAB in this 510 (k) application was found to be substantially equivalent with predicate devices such as the 510(k)-clearance of VectorVision² (K983831).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2001

Mr. Stefan Vilsmeier
President and CEO
BrainLAB AG
Ammerthalstrasse 8
Heimstetten,
Germany

Re: K003589
Trade/Device Name: VectorVision ENT
Regulation Number: 882.4560
Regulatory Class: II
Product Code: HAW
Dated: April 3, 2001
Received: April 5, 2001

Dear Mr. Vilsmeier:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Mill

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003589

Device Name: VectorVision^2 -amendment
(BrainLAB Navigation System)

Indications For Use:

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Example procedures include but are not limited to:

Cranial Procedures:
Cranial biopsies.
Tumor resections.
Craniotomies/ Craniectomies
Skull base procedures.
Thalamotomies/Pallidotomies

for Mark N Miller
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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Spinal Procedures
Spinal implant procedures such as pedicle screw placement.

ENT Procedures:
Transphenoidal procedures.
Intranasal procedures.
Sinus procedures, such as Maximillary antrostomies, Ethmoidectomies, Sphenoidotomies/Sphenoid explorations, Turbinate resections and Frontal sinusotomies

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format I-2-96)